AAHRPP
Association for the Accreditation of Human Research Protection Programs

October 12, 2001

Dear Colleague:

As the newly appointed Executive Director of the Association for the Accreditation of Human Research Protection Programs, I am pleased to announce the release of AAHRPP's Interim Accreditation Standards and Procedures for public review and comment. These standards are the culmination of several years' efforts, which began in 1999 under the leadership of Public Responsibility in Medicine and Research (PRIM&R).

These Interim Standards reflect not only the work of PRIM&R, but also the findings from the Institute of Medicine on accreditation of human research protection programs, *Preserving Public Trust*, and the thoughts and deliberations of many health and institutional review board professionals. AAHRPP plans to use the Interim Standards in its upcoming pilot site visits.

AAHRPP is sharing the Interim Standards with professionals involved in conducting or reviewing human research, like yourself, with the intention of seeking your comments. These public comments, as well as input that we glean from the pilot site visits, will be used in finalizing the standards.

We encourage you to send your comments via e-mail to accredit@aahrpp.org. If you are unable to use e-mail, please send them to 915 15th Street, NW, 9th Floor, Washington, DC 20005. If you would like a print copy of the Interim Standards, please call our office at (202) 783-1112 or e-mail us at accredit@aahrpp.org. We must receive your comments **no later than December 3** to ensure that they will be considered during our review process.

I look forward to hearing from you. We are committed to developing a new accreditation system to ensure that all research involving human participants—which holds so much promise to improve health and well-being—will be carried out ethically and safely.

Sincerely,

Marjorie A. Speers, Ph.D.
Executive Director

# AAHRPP

## ASSOCIATION FOR THE ACCREDITATION

## OF

## HUMAN RESEARCH PROTECTION PROGRAMS

INTERIM ACCREDITATION STANDARDS AND PROCEDURES

SEPTEMBER 2001

**ASSOCIATION FOR THE ACCREDITATION OF HUMAN RESEARCH PROTECTION PROGRAMS**

**AAHRPP ACCREDITATION STANDARDS AND PROCEDURES**

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## SECTION 1

## INTRODUCTION

The goal of voluntary accreditation of an Organization's Human Research Protection Program (HRPP) is to improve the systems that protect the rights and welfare of individuals who participate in research. Accreditation, however, will do more than enhance the systems for protection for individuals. It will help communicate to the public the strength of an Organization's commitment to the protection of human research participants. It will promote high quality research, which will in turn result in better scientific outcomes. Moreover, the organizational processes for meeting the standards and the self-study prompted by the accreditation process will help achieve the dual goals of education and quality improvement. To help promote these goals, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) has adopted nine principles for accreditation of HRPPs. (Table 1) These nine principles serve as the foundation for the structure and content of the accreditation standards set forth below.

In its approach to accreditation, AAHRPP recognizes that although law and regulation provide a legal framework for protecting human research participants, they are not in and of themselves sufficient to protect the rights and welfare of participants. Accordingly, meeting legal and regulatory requirements is merely the threshold: a Human Research Protection Program seeking accreditation must aim to meet ethical standards that transcend legalistic regulation. The standards themselves are designed to help organizations to consistently meet ethical expectations for protecting individual participants yet be flexible enough to account for the diverse institutional and cultural contexts in which intellectual inquiry occurs. They should help promote HRPPs of the highest quality, without the excess baggage of needless bureaucracy. Throughout the AAHRPP accreditation standards, the humanity of research participants is embraced.

The AAHRPP standards and the accreditation process have their philosophical foundations in the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research,[1] which provided the foundation for the federal regulations protecting human research participants in the United States – the Common Rule. That Rule, codified at 45 CFR part 46 (Subpart A) and 21 CFR parts 50 and 56, has been adopted by seventeen federal agencies that conduct, sponsor or regulate research. Under the AAHRPP standards for accreditation, each entity -- whether academic institution, external sponsor, investigator, IRB, or agency -- remains responsible for identifying and determining which federal, state, and local laws apply to its activities and for meeting those applicable requirements. The standards reference relevant laws, regulations and regulatory guidance documents in order to facilitate the integration of compliance activities for programs that also are seeking accreditation.

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[1] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1978); National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Report and Recommendations: Institutional Review Boards (1978).

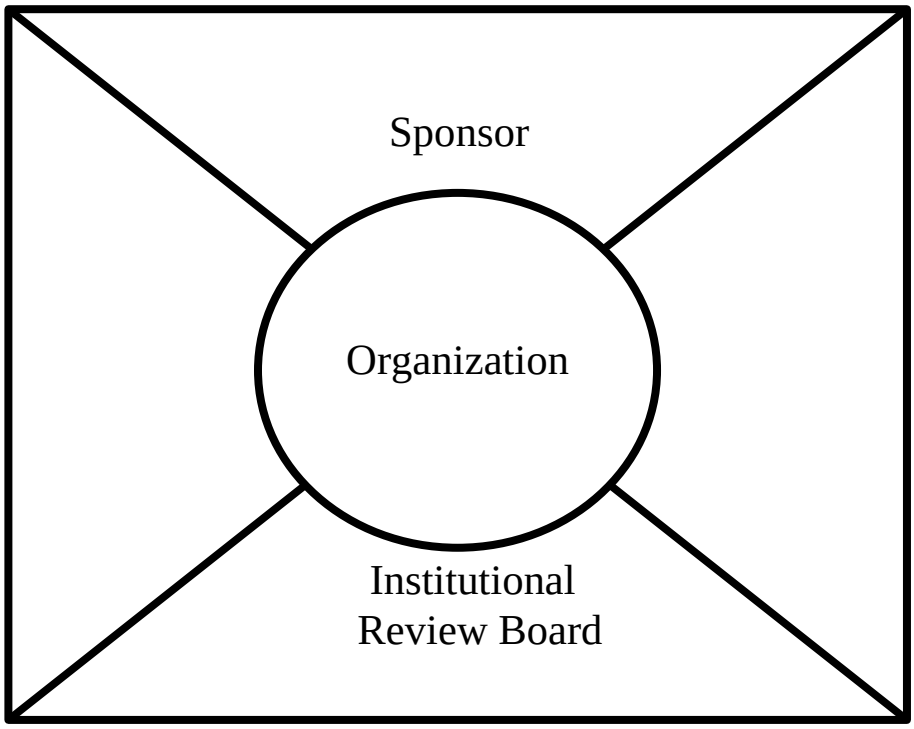
**Table 1**

**AAHRPP PRINCIPLES FOR ACCREDITATION OF HUMAN RESEARCH PROTECTION PROGRAMS**

1. Regulatory compliance is a minimal expectation for a Human Research Protection Program (HRPP).
2. The welfare of human research participants must be a research organization's first priority. Beyond assessing compliance with applicable regulations, accreditation standards should promote a research environment where ethical, productive investigation is valued.
3. Accreditation must approach the HRPP program from a broad organizational perspective, moving beyond a narrow focus upon Institutional Review Board (IRB) operations to examine whether policies and procedures of the organization as a whole result in a coherent, effective scheme for the protection of human research participants.
4. The accreditation process should be flexible and responsive to changes in federal and state regulation of research. The accreditation process must also accommodate continuing evolution of the standards in response to growing experience in their application across the multiple disciplines and settings in which research involving human participants takes place.
5. Accreditation should be primarily an educational process involving collegial discussion and the provision of constructive feedback. The accreditation process must identify areas, in which an HRPP program does not yet meet established standards, and it should afford inspected organizations the opportunity to discuss potential program improvements.
6. Standards should be performance standards, assessed through an evaluation scheme that is sufficiently detailed to support the accreditation process, yet capable of effective and efficient implementation. Program evaluation should result in a grade of pass or fail for each standard, but should also include commendations or recommendations for meeting standards, as appropriate.
7. Standards should be applicable to HRPP programs across the full range of settings (e.g., university-based biomedical, behavioral and social science research, independent IRBs, VA hospitals, and others). Standards should address any special concerns (e.g., the use of vulnerable populations or heightened risk to privacy and confidentiality) that may arise in each setting.
8. The accreditation process should provide a clear, understandable pathway to accreditation, along with equally clear pathways for appeal and the remediation of identified shortcomings.
9. Standards should promote the development and implementation of outcome measures that can provide a basis for demonstrating quality improvement over time.

The structure of the AAHRPP standards owes much to the analysis offered by the Institute of Medicine in its report Preserving the Public Trust: Accreditation and Human Research Participant Protection Programs (2001). The model underlying AAHRP's approach to voluntary accreditation (Figure 1) shows the five different structural domains of a highly developed human research program: Organization, IRB, Investigator, Sponsor and Participant. The domains refer to different areas of responsibility that must be addressed by a Human Research Protection Program.

**FIGURE 1: DOMAINS OF A HUMAN RESEARCH PROTECTION PROGRAM**




Meeting the requirements for all five domains is the responsibility of the entity seeking accreditation for an HRPP – the domains do not refer to separate persons or entities. Rather, to use the model productively, one must think of the domains as they relate to an organization's HRPP. At its simplest level a human research program may consist of little more than a relationship between a single investigator and a single human subject. More highly developed programs may include some or all of the domains as separate organizational departments or functions. Others that involve collaborative ventures or external sponsorship of research may encompass multiple entirely independent entities with differing lines of accountability and degrees of commitment to the HRPP that is seeking accreditation. Under these standards, an accredited organization assumes responsibility for any research relationship with such studies or their investigators.

Under the AAHRPP accreditation program, although the standards are organized into distinct domains, in the end, it is the organization applying for accreditation of an HRPP that is responsible for establishing the policies and procedures to meet each of the standards. For purposes of these standards, we use the term "human research protection program" or "HRPP" to refer to the accreditable unit of the organizational entity seeking accreditation, together with any external arrangements that make up its program. That is, most entities that operate human research programs also are involved in other activities that are not directly related to their research activities: universities are involved in teaching, hospitals are involved in patient care and community outreach, entities that operate Independent Review Boards have corporate functions, and technology companies are involved in marketing and distribution activities. In addition, some research programs arrange for legally separate entities to fulfill critical roles in their research programs, such as a government agency or research institution's contractual arrangements for review by IRBs operated by an independent organization. Identifying -- and protecting -- HRPP activities from the other critical missions of the organization seeking accreditation will be an important responsibility for each entity seeking accreditation for its human research protection program.

The AAHRPP standards are built on the presumption that a Human Research *Protection* Program requires, *at a minimum*, three systems of relationships: investigator, IRB and participant. At least since the enactment of the National Research Act,[2] publication of the Commission reports, and federal agencies' adoption and codification of the Common Rule, IRBs have played a central role in the protection of human research participants: IRBs provide independent review of an investigator's research proposal. In AAHRPP's view, however, accreditation standards must affirm the role of IRBs in protecting research participants and at the same time have a more realistic approach to dealing with the complex institutional and corporate environment in which sophisticated research takes place today. Although a significant portion of human research continues to be conducted in largely self-contained institutional settings with complex and unique structures, funding arrangements, and lines of accountability, more and more research is being conducted outside traditional institutional settings or involves the collaboration of investigators who are accountable to different institutions or corporate entities. The AAHRPP accreditation standards are designed to account for all five domains of a human research protection program -- organization, investigator, IRB, sponsor and participant. As discussed more fully in Section 4, the AAHRPP accreditation standards offer the flexibility and scalability necessary for accreditation of research programs of any size and complexity, and provide a tool to educate personnel and improve operations through self-study and evaluation. External accreditation is offered to complement an organization's education and quality improvement activities. The process of external accreditation, with site visits, grades and certificates also serves to inform the public regarding a human research program's current efforts to maintain and to continuously improve its high standards in protecting research participants.

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[2] National Research Act, Pub. L. 93-348, 88 Stat. 342 (1974). The National Research Act created the National Commission for the Protection of Human Subjects; it also required that all entities receiving grants from the Department of Health, Education and Welfare (now HHS), establish Institutional Review Boards.

## SECTION 2

## LEGAL AUTHORITIES AND SOURCE MATERIALS

These Standards are grounded in principles articulated in the Belmont Report and, more recently, with a different form, audience and purpose, in the revised Declaration of Helsinki.[3] The Standards themselves go beyond the draft standards developed by Public Responsibility in Medicine and Research ("PRIM&R"), which focused on medical research,[4] and the standards developed by the National Commission for Quality Assurance (NCQA), which focused on the accreditation of Department of Veterans Affairs research programs.[5] The AAHRPP Standards are designed for application to a broader range of research institutions than those articulated by NCQA, and to more diverse types of research than the medical research targeted by PRIM&R.

The AAHRPP standards assume, as a baseline, that HRPPs will comply with applicable federal, state, and local laws and regulations. Each entity involved in a human research program is responsible for identifying and complying with the laws and regulations applicable to its activities. The AAHRPP standards are not designed to duplicate or summarize the applicable laws, nor should accreditation be deemed to suffice as an institution's compliance program for legal purposes. To assist entities in building human research protection programs on their current compliance programs, primary sources of law and regulatory guidance are identified with each standard, where applicable. We have not attempted to identify all of the relevant federal, state or local laws. The applicable state and local laws vary from one institution to the next, and even the applicable federal law may differ for projects depending upon the specific research population and area of research.[6] Section 4, which presents each of the Standards and their component Elements, introduces each Domain with a list of regulatory authorities that provide the regulatory foundation on which each Domain is established. Principal regulatory sources cited in the standards include:

1. Federal regulations and related guidance, including

   A. U.S. Department of Health and Human Services ("DHHS") regulations at 45 CFR part 46 (Sub-part A of which is the "Common Rule")

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[3] World Medical Association, World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (amended Oct. 2000).

[4] PRIM&R, Committee on Assessing the System for Protecting Human Research Subjects, PRIM&R Accreditation Standards – Final Draft (Feb. 2001).

[5] NCQA, VA Human Research Protection Accreditation Program Draft Accreditation Standards for Public Comment (March 30, 2001).

[6] However, we note that it is increasingly likely for states to have privacy and/or informed consent laws – particularly consent to genetic testing -- that apply to research that is subject to their jurisdiction.

DHHS Office for Protection from Research Risks ("OPRR") Institutional Review Board Guidebook (1993)
DHHS Office of Human Research Protection ("OHRP"), Compliance Activities: Common Findings and Guidance

OPRR, "Dear Colleague Letters"

B. U.S. Food and Drug Administration ("FDA") regulations at 21 CFR parts 50, 56, 312 and 812

FDA Information Sheets; policy statements and guidance documents on website

FDA, International Conference on Harmonization; Guidance on General Considerations for Clinical Trials, 62 Fed. Reg. 66113 (Dec. 17, 1997.

2. International Conference on Harmonization, Good Clinical Practice Guidelines

3. DHHS Medical Privacy Regulations at 45 CFR part 164, implementing the Health Insurance Portability and Accountability Act (HIPAA)

4.State laws regulating privacy, informed consent and research ethics are not cited apart from notation of the likely areas in which they apply.

Entities seeking accreditation for HRPPs may find it useful to review the legal source documents; guidance documents found on the website of the DHHS Office of Human Research Protections (OHRP) http://ohrp.osophs.dhhs.gov/; the NIH Bioethics website http://www.nih.gov/sigs/bioethics/; the Food and Drug Administration (FDA) guidance regarding IRBs that review clinical trials for drugs, devices and biologicals http://www.fda.gov/cder/guidance/ http://www.fda.gov/cdrh/ochome.html http://www.fda.gov/cber/guidelines; documents such as the Belmont Report, as well as recent reports on research with human participants and the role of the IRB published by the Institute of Medicine,[7] the DHHS Inspector General,[8] the General Accounting Office, and the National Bioethics Advisory Commission.[9]

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[7] Institute of Medicine, Preserving Public Trust: Accreditation and Human Research Participant Programs (April 17, 2001).

[8] DHHS Office of Inspector General, Protecting Human Research Subjects: Status of Recommendations (April 2000).

[9] National Bioethics Advisory Commission, Ethical and Policy Issues in Research Involving Human Participants (August 20, 2001).

**Table 2**

**Abbreviations Used For Regulatory Sources:**

CFR = Code of Federal Regulations
DHHS = U.S. Department of Health and Human Services
IRB-GB = OPRR IRB Guidebook
FDA = U.S. Food and Drug Administration
FDA-IS = FDA Information Sheets
FDA-IS, (CL) = Appendix H: A Self-Evaluation Checklist for IRBs
FDA-IS, (FAQ) = Frequently Asked Question
FDA-IS, (ICG) = The Guide to Informed Consent
FDA-IS, (CR) = Continuing Review After Study Approval
FDA-IS, (SR/NSR) = Significant Risk and Nonsignificant Risk Medical Device Studies
ICH-GCP = International Conference on Harmonization, Good Clinical Practice Guidelines
OHRP-CFG = Office of Human Research Protection Compliance Activities: Common Findings and Guidance (Sept. 1, 2000)
HHSIGR = DHHS Inspector General's Report
HIPAA = Health Insurance Portability and Accountability Act of 1996

## SECTION 3

## DEFINITIONS

ADVERSE EVENT (AE) – Any untoward occurrence in a research participant. The occurrence need not have a clear causal relationship with the individual's participation in the research; an AE can be any unfavorable and unintended sign, symptom or disease affecting a participant's physical, mental or emotional health or well-being. See, e.g., 21 CFR 312.32(a); 21 CFR 812; 1RB-GB, G-1.

> -- SERIOUS ADVERSE EVENT (SAE) – Any event that results in death, a life-threatening situation, hospitalization or prolonged hospitalization, persistent or significant disability/incapacity or a congenital anomaly/birth defect. SAEs require prompt (expedited) reporting to the Sponsor, the FDA and the IRB.
>
> -- UNEXPECTED ADVERSE EVENT (UAE) – Any adverse event that was unanticipated or not previously observed (e.g., not included in the consent form or investigator brochure). This includes adverse effects that occur more frequently or with greater severity than anticipated. Events that are unexpected and serious require expedited reporting to the Sponsor, the FDA and the IRB

ASSENT – The agreement of a child, or an adult who lacks full decision-making capacity or legal authority to consent to participate in research.

CAPACITY (for making healthcare decisions) – Often defined in state statutes – generally understood as the ability to understand the choice(s) presented, to appreciate the implications of choosing one alternative rather than another, and to make – and communicate – a choice.

CERTIFICATE OF CONFIDENTIALITY – An advance grant of confidentiality issued to a research study by the Public Health Service in certain circumstances, which is intended to provide protection against forced disclosure, even against a subpoena of individually identifiable research data.

DATA AND SAFETY MONITORING BOARD (DSMB) – A group of scientists, physicians, statisticians and others, independent of the research project, who collect and analyze data and critical endpoints of a research protocol at specified intervals and recommend whether to continue, modify, or terminate that research.

DECISION-MAKING CAPACITY – <u>See</u> capacity (for making healthcare decisions).

FDA FORM 483 – Form used by FDA inspectors to report on a site visit.

FDA FORM 1572 – Agreement with the federal government signed by the Principal Investigator and specifying the responsibilities of an investigator in conducting research including compliance with laws and regulations protecting human subjects and assuring the integrity of research data.

FDA FORM 3454 – The financial certification form required by the FDA regarding financial interests and the investigators' relationships with a sponsor of clinical trials regarding a drug, biologic, or device.

FEDERAL-WIDE ASSURANCE (FWA) – An agreement between a research institution and OHRP that stipulates method(s) by which the Organization will protect research participants.

HUMAN RESEARCH PROTECTION PROGRAM (HRPP) – A system that includes all components critical to protecting individuals studied in research and that is managed in accordance with these standards and with applicable federal, state and local laws and regulations. In general, the HRPP includes: a central authority, Institutional Review Board(s) (IRB), IRB staff, investigators and research personnel, and sources of funding. Some components of the HRPP may be external to the Organization seeking accreditation, but the essential components of an HRPP should be identifiable in all cases.

HUMAN SUBJECT/PARTICIPANT – A living individual about whom a research investigator (whether a professional or a student) obtains data through intervention or interaction with the individual or from individually identifiable information. 45 CFR 46.102(f).

INDIVIDUAL AUTHORIZATION – Written permission by an individual who is the subject of health or private information that permits the use and/or disclosure of such information for research, as required by 45 CFR 164.508.

INFORMED CONSENT – An agreement to participate in research that is made voluntarily by an individual with legal and mental competence and the capacity to understand the information transmitted and its implications, after having been informed of the physical, psychological and personal risks and potential benefits entailed by a research protocol. Informed consent is usually demonstrated by signing a consent form, but it may be oral (under specific criteria approved by an IRB). 45 CFR 46.116

INSTITUTIONAL REVIEW BOARD (IRB) – An independent committee comprised of at least 5 scientific, non-scientific, and non-affiliated members established according to the requirements outlined in Title 45, part 46 and Title 21, part 56 of the U. S. Code of Federal Regulations. The term includes, but is not limited to Institutional Review Boards, Central Review Boards, Independent Review Boards, and Cooperative Research Boards.

INVESTIGATIONAL DEVICE EXEMPTION (IDE) – The exemption by which the FDA permits a device that otherwise would be required to comply with a performance standard or to have premarket approval, to be shipped lawfully in interstate commerce for the purpose of conducting investigations of that device. See 21 CFR part 812.

INVESTIGATIONAL NEW DRUG (IND) –An investigational drug or biologic application by which the FDA allows testing in human beings of a substance having an effect in the body. See

21 CFR part 312, subpart B. The FDA issues an IND number after approving an IND submission.

> INVESTIGATOR– An individual(s) who has responsibility for the design, conduct, data collection, management, analysis, or reporting of research; and has responsibility for supervising staff and carrying out a protocol at a specific site. In clinical trials, a person who actually conducts an investigation.
>
> --PRINCIPAL INVESTIGATOR (PI)—An individual who is accountable for the overall conduct of a particular research protocol. See 21 CFR § 50.3(d).
>
> --CLINICAL RESEARCH COORDINATOR/RESEARCH STAFF – Individuals who are delegated responsibility by the Investigator for specific research tasks.

LEGALLY AUTHORIZED REPRESENTATIVE – An individual, judicial or other body authorized under applicable law to consent on behalf of a prospective participant to that individual's participation in research. See 21 CFR § 50.3(l).

MINIMAL RISK – Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the participant's daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR § 46.102(i); 21 CFR § 50.3(k).

MULTIPLE PROJECT ASSURANCE (MPA) – An agreement between an institution and OPRR that stipulates the method(s) by which the Organization will protect the rights and welfare of research participants. (Under OHRP, MPAs will be replaced by FWAs. See 66 Fed. Reg. 19139, 19141 (April 13, 2001).)

PARTICIPANT – See "Human Subject/Participant."

PRINCIPAL INVESTIGATOR (PI): See INVESTIGATOR.

PROTOCOL – A formal plan that includes, at minimum, the objectives, rationale, design, methods and other conditions for the conduct of a research study. See ICH-GCP.

PROTOCOL FILE – The documents maintained by the IRB office, and by the investigator, containing the protocol, copies of approved consent forms, investigator's brochure, IRB/investigator communications and all other supporting materials for a research study.

RESEARCH - Systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge, including any use in human beings of a drug or device requiring approval or registration by FDA prior to marketing. See 45 CFR § 46.102(d). (Compare to definition of "clinical investigation" in 21 CFR § 50.3(c).)

SAFETY REPORTS (for IND and IDE) – Written reports from sponsors notifying the Food and Drug Administration and all participating investigators of any adverse experience associated with the use of a drug, biologic or device that is both serious and unexpected.

SPONSOR – A person or entity that initiates, funds, or is responsible for a research study. Under some circumstances, e.g., cooperative agreements, as well as some commercially sponsored research, a sponsor also may participate in conducting the study. A sponsor may be an individual; a pharmaceutical company, device manufacturer, or other company; a governmental agency; an academic institution; a foundation or other public or private organization. For research that is regulated by FDA, the sponsor is the entity responsible for meeting FDA requirements in initiating and conducting a study, submitting annual reports and safety reports, and in preparing and presenting an application for approval to market a new drug or device. See 21 CFR § 50.3(e).

UNANTICIPATED PROBLEMS (UP) - As distinct from adverse events, any unplanned occurrence that may affect the risks and/or potential benefits involved in the research study. Unplanned occurrences are usually related to study design or methods. Such occurrences can be favorable or unfavorable to participants and may or may not influence the study objectives or results (e.g., loss of identifiable data).

VULNERABLE SUBJECTS/PARTICIPANTS – Individuals who lack the capacity to provide informed consent or whose willingness to participate in research may be unduly influenced by others. Vulnerable subjects include, for example, children, prisoners, individuals with emotional or cognitive disorders/impairments, and economically or educationally disadvantaged persons.

## SECTION 4

## AAHRPP STANDARDS

## THE FIVE DOMAINS

The AAHRPP standards allocate the criteria for accreditation of Human Research Protection Programs into the following five *Domains*:

Organization IRB Investigator Sponsor Participant

The "Organization" is the legal entity that assumes responsibility for the human research program and applies for accreditation. The legal entity may be an academic medical center, university, clinic, hospital, managed care organization, contract research organization, or a corporate entity such as a pharmaceutical or biotechnology company, or an independent entity that operates Research Review Boards. Despite great dissimilarities in how such entities are structured, the Organization domain identifies those elements that must be evident, albeit in various different forms, in an entity that seeks accreditation for its human research program.

The domain of the "Institutional Review Board" (IRB) refers to the arrangements that the Organization has made for an *independent* review of ethical and scientific aspects of each research protocol involving human participants. This review and the other activities of the IRB are concerned with protecting the rights and welfare of the participants.

The "Investigator" domain includes the various arrangements that the Organization has made for assuring that individuals who plan to conduct research – whether as a principal investigator, a sub-investigator, or member of a research staff – understand and fulfill their responsibilities. At bottom, these responsibilities stem from the fact that an individual who engages in such research is participating in arrangements that intentionally expose other human beings to some degree of risk -- whether physical, psychological or social -- for scientific purposes.

The "Sponsor" domain includes the Organization's arrangements for structuring its relationships with those who fund research, such as federal agencies, universities' faculty-grant programs, foundations, and corporations (e.g., pharmaceutical, device, biotechnology, and genomics companies). A sponsor may be either an internal or external sponsor. For example, a pharmaceutical company may be an external sponsor to a university researcher, but an internal sponsor to scientists who conduct its own human research program. A single investigator at an academic medical center may have industry funding, a faculty research grant, and support from a federal agency in relation to a specific clinical study, or related studies. What is critical for the Organization seeking accreditation is that it identifies and addresses requirements with all sponsors, internal and external. In general these requirements include, but are not limited to, issues of scientific integrity, the ethical conduct of research, publication of results, conflict of interest, intellectual property, availability of medical care to research participants, and indemnification.

The "Participant" domain refers to the arrangements that the Organization has made for understanding the cognitive, social, psychological and physical needs and concerns of its research participants and for providing them with tools and resources to assume an active, responsible role in research.

There is no single "right" way for integrating the five domains into a high-caliber human research protection program. Rather, each entity seeking accreditation will evidence its own unique approach to meeting the various standards. Altogether, there are twenty-two AAHRPP Standards within 5 Domains. Each *Domain* is introduced by general commentary and a statement of the Standards relevant to that domain. Each Standard is followed by one or more Elements. AAHRPP will provide training and guidance to site visitors regarding how to observe and document strengths and deficiencies in performance with respect to the Elements.

## DOMAIN I: ORGANIZATION

**COMMENTARY:** The organizational domain describes structural characteristics of the legal entity that assumes responsibility for the human research protection program and that applies for accreditation. The organizational structure is what implements the HRPP's responsibilities for establishing and maintaining an environment dedicated to the ethical principles for safeguarding the rights and welfare of the human beings recruited to participate in research activities. These broad responsibilities can be met by establishing a formal process to monitor, evaluate, and continually improve the protection of human research participants; dedicating resources sufficient to do so; exercising oversight to ensure appropriate supervision of research; educating research staff about their ethical responsibility to protect research participants; and, where appropriate, providing a mechanism to intervene in research and to respond directly to concerns of research participants.

**REGULATORY FOUNDATION**

21 CFR 50.23(a)
21 CFR 50.24
21 CFR Part 54
21 CFR Part 312
21 CFR Part 812
45 CFR Part 46.103
45 CFR Part 46.103(b) – (f)

**GUIDANCE DOCUMENTS:**

FDA-IS, (FAQ)(I)
FDA-IS, (ICG)
FDA-IS, (FAQ)(III)(24)
ICH-GCP 5.1
IRB-GB, (I)(B)
IRB-GB, (I)(B)(D)
IRB-GB, (II)(ii)
OHRP – CFG; other requirements
Office for Research Integrity, Notice of Proposed Rulemaking, 65 Fed. Reg. 70830 (2000)

**STANDARD I-1: The Organization has a systematic and comprehensive Human Research Protection Program (HRPP) with appropriate leadership.**

**ELEMENTS**

I.1.A. The Organization has a written description of (or plan for) its human research protection program (HRPP) appropriate for the volume and nature of the research involving human participants conducted under its auspices.

I.1.B. The Organization places responsibility for the HRPP in an official with sufficient standing and authority to ensure implementation and maintenance of the program.

I.1.C. The Organization has a plan for working with sponsors, investigators, participants and IRBs to foster a culture of research integrity.

**STANDARD I-2: The Organization assures the availability of resources sufficient to ensure the rights and welfare of human research participants, taking into consideration the research activities in which they are asked to participate.**

**ELEMENTS**

I.2.A. The Organization provides for the number of IRBs appropriate to the volume and types of human research to be reviewed. An Organization may use the IRB(s) of another Organization to meet the needs of its research program.

I.2.B. The Organization assures that the resources available to the HRPP are sufficient for conducting the activities that are under its jurisdiction.

I.2.C. The Organization assures that the research, patient care and safety resources are fully adequate for the conduct of the research.

**STANDARD I-3: The Organization exercises oversight to assure compliance and ensure appropriate IRB review.**

**ELEMENTS**

I.3.A. The Organization has clear, written policies and procedures governing research with human participants available to every investigator and potential investigator affiliated with the Organization.

I.3.B. The Organization has policies and procedures to identify, manage and minimize individual conflicts of interest of investigators and of IRB members.

1.3.C. The Organization has policies and procedures to identify, manage and minimize institutional conflicts of interest that may affect its relationship with the IRBs that review research, with investigators and with sponsors.

I.3.D. The Organization maintains and implements written policies and procedures for addressing allegations and findings of non-compliance with HRPP requirements.

I.3.E. The Organization maintains and implements written policies and procedures for addressing serious and unanticipated risks to research participants or others.

I.3.F. If it receives federal research funds, the Organization maintains and supports a current and approved Federal-wide or other Assurance that identifies its principles and guidelines for protecting human research participants.

I.3.G. The Organization implements a plan to measure and improve HRPP effectiveness, quality, and compliance with organizational and external standards, including federal, state and local laws.

**STANDARD I-4: The Organization ensures that all personnel reviewing, conducting or supporting human research (including IRB members and personnel involved in the HRPP) demonstrate and maintain sufficient knowledge of the protection of research participants.**

**ELEMENTS**

I.4.A. The Organization evaluates and contributes to the improvement of the qualifications and training of individuals, including IRB members and staff, that it vests with responsibility for protecting the rights and welfare of human research participants.

I.4.B. The Organization ensures that investigators and all relevant research staff affiliated with the Organization receive education regarding their obligation to protect the rights and welfare of human research participants.

**STANDARD I-5: The Organization ensures that the use of any investigational or unlicensed substance or material that is to be administered to, or implanted in, the body of a human research participant is consistent with FDA and other Federal regulations, guidelines and requirements**

ELEMENTS

I.5. A. The Organization secures assurances from the sponsor that the manufacture and/or formulation of investigational (or unlicensed or unapproved) drugs, biologicals, or devices to be furnished for use by a human research participant conform to FDA and other federal regulations.

I.5. B. The Organization has policies and procedures for handling investigational (or unlicensed or unapproved) drugs, biologicals, or devices that are furnished for use by a human research participant, including policies on disposition of unused products. These policies and procedures relate to pharmacy and inventory control processes and documentation.

I.5. C. The Organization ensures that human participants are not exposed to investigational (or unlicensed or unapproved) products without an IRB approved protocol and a signed informed consent form or documentation of compliance with FDA regulations governing research on products designed for use in emergency interventions.

## DOMAIN II: IRB

**COMMENTARY:** An Institutional Review Board (IRB) is a body established under federal regulations to protect the rights and welfare of human research participants. It is critical that the HRPP have mechanisms in place to assure the independence of its IRBs with respect to IRB decision-making. IRB structure, composition, operations, and review standards are set forth in the Common Rule and FDA regulations. A major IRB responsibility is to assure that the risks of proposed research are justified by the potential benefits to the participants and to society, and that risks are minimized to the extent possible consistent with sound research design. In addition, the IRB must assure that the risks of research do not fall disproportionately on one group while the potential benefits accrue to another. IRBs oversee the consent process to assure voluntary and knowing consent to participate in research. Individuals who are particularly vulnerable or whose capacity to consent may be in doubt require additional protection during the consent process. IRBs must assure that the research is designed to respect individual privacy and preserve the confidentiality of private information. . Finally, IRBs have on-going oversight responsibility of approved research to monitor the welfare of the participants and to determine that the risks and potential benefits remain unchanged. In carrying out its obligations, an IRB may approve, disapprove, or require modifications to research protocols. It also may suspend or terminate its approval of ongoing (previously approved) research. This domain of standards sets forth requirements for IRB membership, training, resources, operations and decision making.

**REGULATORY FOUNDATION**

45 CFR Part 46
21 CFR Parts 50 and 56

**GUIDANCE DOCUMENTS:**

FDA-IS, (FAQ)(II); (V), (VI)
FDA-IS, (CL)
FDA-IS, (ICG)
FDA-IS, (PRS)
FDA-IS, (RSS)
FDA-IS, (SR/NSR)
FWA/MPA
HHS-IGR
ICH-GCP, (3.2.1); (3.3); (3.4); (4.9.4); (8.0)
IRB-GB, (I)(A) & (B); (III)(A) - (D)
OHRP-CFG (G64)
OPRR Rpts. #97-01; 61 Fed. Reg. 51531-51533 (Oct. 2, 1996)

**STANDARD II-1: The IRB's financing, structure and composition are appropriate to the amount and nature of research reviewed.**

**ELEMENTS**

II.1.A. The IRB has a source of financial support and a budget that is adequate to meet its obligations to the HRPP.

II.1.B. The IRB has a qualified IRB chair(s), members and staff, whose membership and composition are periodically reviewed. The IRB administrator, staff, chair(s) and members have knowledge, skills and abilities appropriate to their respective roles.

II.1.C. The IRB membership roster includes sufficient information about members to permit it to have appropriate representation at the meeting for each protocol under review.

II.1.D. The IRB has a system for assuring that protocols are reviewed by individuals with appropriate expertise and that reviewers' potential conflicts of interest are identified and managed.

II.1.E. IRB has a process for recognizing the need for and, when necessary, obtaining additional expertise (e.g., education in or consultation on scientific, ethical, community representation, or other issues) when reviewing a specific protocol.

II.1.F. The IRB meets regularly and members have sufficient time to review materials prior to meeting.

**STANDARD II-2: The IRB systematically evaluates each research protocol to ensure adequate protection of participants.**

**ELEMENTS**

II.2.A. The IRB has policies and procedures regarding the informed consent process that are appropriate for the populations from which research participants are selected.

II.2.B. The IRB has policies and procedures for determining whether research is exempt from IRB review, and appropriately makes such determinations.

II.2.C. The IRB has policies and procedures for conducting expedited initial or continuing review (if applicable), and appropriately conducts such review.

II.2.D. The IRB receives and reviews the relevant information needed to evaluate research proposals during initial review.

II.2.E. The IRB receives and considers relevant information to conduct continuing review of research proposals and, where appropriate, requests changes.

**STANDARD II-3: The IRB maintains adequate documentation of its activities.**

**ELEMENTS**

II.3.A. The IRB maintains a complete set of all materials relevant to the research study in each protocol record/file.

II.3.B. The IRB documents pertinent discussions and all decisions on research proposals and activities.

II.3.C. The IRB retains required records for at least three years following study completion.

**STANDARD II-4: The IRB systematically evaluates risks to participants and potential benefits as part of the initial review and ongoing review of research.**

**ELEMENTS**

II.4.A. The IRB has procedures for conducting initial and continuing review of the risks and potential benefits of research.

II.4.B. The IRB determines whether risks to participants are reasonable in relation to potential benefits.

II.4.C. The IRB has a process for identifying and analyzing potential sources of risk and measures to minimize risk, including risks to a participant's present or future physical health, emotional well being, and personal privacy.

II.4.D.The IRB has and applies policies and procedures for determining the risks to vulnerable populations and, specifically, for determining the required risk categories in protocols involving children and prisoners.

**STANDARD II-5: The IRB systematically evaluates recruitment and participant selection practices.**

**ELEMENTS**

II.5.A. The IRB has policies and procedures to evaluate the equitable selection of participants from various populations and sub-populations and considers whether inclusion and exclusion criteria impose fair and equitable burdens and benefits.

II.5.B. The IRB has policies describing recruitment practices for proposed research.

II.5.C. The IRB reviews proposed participant recruitment methods, advertising materials and participant payment arrangements, and permits them only if fair, honest and appropriate.

**STANDARD II-6: The IRB systematically evaluates the protection of privacy and confidentiality in proposed research.**

**ELEMENTS**

II.6.A. The IRB has policies and procedures to evaluate the proposed arrangements for protecting the privacy of research participants during and after their involvement in the research.

II.6.B. The IRB has policies and procedures to evaluate proposed arrangements for protecting the confidentiality of research data during and after the conclusion of the investigation.

II.6.C. The IRB ensures compliance, where applicable, with regulations requiring individual authorization for identifiable information to be made available for research purposes, including provisions for actions to be taken by investigators in the event of revocation of authorization by an individual.

II.6.D. The IRB has policies and procedures for waiver of authorization requirement.

**STANDARD II-7: The IRB establishes and implements policies and procedures for soliciting informed consent from research participants or their legally authorized representatives.**

**ELEMENTS**

II.7.A. The IRB evaluates each protocol's compliance with policies and procedures on seeking informed consent from participants or their legally authorized representatives.

II.7.B. The IRB reviews the content of the consent process, including the form, the process through which it is obtained from each participant, and the procedures to be followed in the event of revocation.

II.7.C. The IRB assures that the investigator has a process for properly documenting informed consent and its revocation.

II.7.D. The IRB develops and implements policies and procedures for approving waiver or alteration of the consent process.

**STANDARD II-8: The IRB protects human participants in research that is exempt from federal regulations.**

**ELEMENTS**

II.8.A. The IRB has and implements policies and procedures for granting exceptions to the general requirements for obtaining informed consent and appropriately reviews such exceptions.

II.8.B. The IRB has policies and procedures for exceptions from informed consent requirements in planned emergency research and appropriately reviews such exceptions.

## DOMAIN III: INVESTIGATOR

**COMMENTARY**: Investigators' roles and responsibilities are influenced by the environment in which they conduct research and by the type of research they conduct. The presence of a competent, informed, conscientious, compassionate and responsible investigator is the best possible protection for all in the research process. This domain of standards sets forth requirements for investigators and other research personnel involved in research with human beings. As part of its HRPP, an Organization can improve its protection of research participants if it has arrangements for ascertaining and ensuring the competence of investigators, whether internal or external to the program.

**STANDARD III-1: When designing studies or conducting human research, Investigators understand and apply underlying ethical principles as described in the Belmont Report. In designing and conducting clinical trials, Investigators follow Good Clinical Practice guidelines defined by the Food and Drug Administration.**

**ELEMENTS**

III.1.A. The Organization has a mechanism for identifying, managing and minimizing Investigator conflicts of interest that may affect the Investigator's relationship with the participant and/or the outcome of the research, and is able to demonstrate the effectiveness of Investigator compliance.

III.1.B. The Organization has a process for encouraging Principal Investigators (PIs) to incorporate study design and reporting mechanisms that provide information relevant to monitoring the rights and welfare of participants enrolled in their research, and is able to demonstrate the effectiveness of investigator compliance.

III.1.C. The Organization has a process for encouraging Investigators to thoroughly evaluate less risky alternatives, and identify ways to detect harm promptly and mitigate any injuries before proposing research that poses physical risks to participants.

III.1.D. The Organization has a process for holding Investigators accountable for conducting research with human beings only when supported by adequate resources.

III.1.E. The Organization has a process for assuring that wherever feasible, Investigators design research using informed consent to obtain data from participants.

III.1.F. The Organization has a process for ensuring that Investigators are responsive to participants' complaints and/or requests for information, and is able to demonstrate compliance.

III.1.G. The Organization has evidence that Investigators understand and assume the responsibility of being Investigators.

**STANDARD III-2: Investigators meet requirements for conducting research with human beings and comply with all applicable federal, state and local regulations and guidelines for protecting research participants.**

**ELEMENTS**

III.2.A. Investigators are qualified by training and experience for their research role.

III.2.B. Investigators use of investigational products in human participants is consistent with FDA requirements.

III.2.C. The Organization has mechanisms for assuring that investigators assess and report adverse events in accord with applicable law, regulations, and IRB policies.

III.2.D The Organization assures that PIs maintain appropriate oversight of their research protocols, recruitment, selection of study participants, and study conduct.

## DOMAIN IV: SPONSOR

**COMMENTARY:** A sponsor is the individual, company, institution or organization responsible for the initiation, management and/or financing of a research study. What is critical for the Organization seeking accreditation is that it identify and address requirements with all sponsors, internal and external. In general these requirements may include, but not be limited to, issues of scientific integrity, the ethical conduct of research, publication of results, conflict of interest, intellectual property, availability of medical care to research participants, and indemnification. The Organization, as part of its HRPP, should apply its standards for sponsors to its oversight and review of externally sponsored research protocols.

### REGULATORY FOUNDATION

21 CFR part 54

**STANDARD IV-1: The Organization demonstrates its ability to involve external sponsors in its program to protect the rights and welfare of research participants.**

### ELEMENTS

IV.1.A. The Organization has a mechanism for eliciting sponsors' involvement in fostering a culture of research integrity.

IV.1.B. The Organization secures the sponsors' agreement to use procedures that protect research participants.

**STANDARD IV-2: The Organization has a mechanism for ensuring that Sponsors assume responsibility for ensuring that studies are organized, managed and documented in compliance with the protocol and applicable regulatory requirements and, where applicable, implement and maintain quality assurance and control systems.**

### ELEMENTS

IV.2.A. Agreements between the Sponsor and the investigator/institution or any other parties involved in implementing the research protocol are in writing.

IV.2.B. The Organization and Sponsor have an agreement that in selecting investigators affiliated with the Organization, the Sponsor will assure that the research team is appropriately trained and qualified to conduct the research.

IV.2.C. The Organization has an agreement with the Sponsor that informed consent and individual authorization forms meet the Organization's requirements and comply with state and local, as well as applicable federal laws.

IV.2.D. The Organization has an agreement with the Sponsor that case report forms meet organizational standards for maintaining confidentiality of participants as well as accuracy and integrity of data.

**STANDARD IV-3: The Organization has procedures for assuring that Sponsors cooperate in a timely fashion in communicating information that may affect the on-going oversight of a protocol by the HRPP.**

**ELEMENTS**

IV.3.A. The Organization has an agreement with the Sponsor that the Sponsor promptly reports any serious or unexpected adverse events to all investigators, institutions and regulatory authorities that are involved with a protocol and provides regular reports of adverse reactions in accordance with FDA regulations.

IV.3.B. The Organization has an agreement with the Sponsor that the Sponsor reports to investigators, IRBs and institutions involved with a protocol any developments that may affect the HRPP and its responsibility for ongoing monitoring of an approved research project, any proposed changes to the protocol, including participant recruitment methods, and any information needed for the IRB's continuing review.

IV.3.C. The Organization has an agreement with the Sponsor that the Sponsor provides information needed to document the Organization's compliance with applicable law, regulations, and federal agreements.

**STANDARD IV-4: The Organization assures that the Sponsor discloses compensation and other relationships with investigators and research institutions that could give rise to conflicts of interest.**

**ELEMENTS**

IV.4.A. The Organization has an agreement with the Sponsor that the Sponsor will require investigators to disclose to the Organization and the Sponsor, all compensation, consulting agreements and financial interests that may be affected by the outcome of the sponsored research protocol.

IV.4.B. The Organization has an agreement with the Sponsor that the Sponsor makes available information regarding its relationships with and/or support of any

research component of the Organization separate from its support of a sponsored research protocol.

**STANDARD IV-5: The Organization has procedures for ensuring that Sponsors respect the integrity of research and the academic freedom of investigators.**

## ELEMENTS

IV.5.A. Where a research grant has been awarded to an affiliated investigator, the Organization has a mechanism to avoid undue influence by the Sponsor on the design, conduct or reporting of the research, or selection of research participants.

IV.5.B. Sponsored research agreements preserve the investigators' and the Organization's authority to conduct human research ethically and to protect participants.

IV.5.C. Sponsored research agreements respect and adhere to the Organization's policies concerning investigators' rights and accountability for independent inquiry and publication.

IV.5.D.The Organization has procedures for dealing fairly with the rights of investigators, sponsors, participants, and research institutions in matters relating to discoveries with potential commercial value.

## DOMAIN V: PARTICIPANTS

**COMMENTARY:** Under the principles established in the Belmont Report, the research participant domain has focused primarily on obtaining and documenting informed consent. Enhancing the involvement of research participants at every stage of the research endeavor can result in numerous benefits -- from helping to minimize participant risk to improving recruitment and retention. Institutions, organizations and individuals should aim to enhance the involvement of research participants by drawing directly from their knowledge and experience, not only to ensure that consent is informed and freely given, but also to improve the design, selection, review and monitoring of research. The objective is to build research programs that participants reward with their confidence, enthusiasm, and desire to help investigators pursue sound, ethical science.

**STANDARD V-1: The Organization is responsive to the concerns of research participants.**

**ELEMENTS**

V.1.A The IRB assures that each protocol provides a mechanism for research participants to ask questions and voice concerns or complaints.

V.1.B. The Organization ensures a safe, confidential and reliable channel for participants and/or their representatives to discuss problems, concerns, and questions with an informed individual who is not affiliated with administration of the research protocol in which they are enrolled.

V.1.C. The Organization has a mechanism for incorporating participants' and/or prospective participants' views regarding recruitment, research conduct and protocol oversight.

**STANDARD V-2: The Organization has a mechanism for educating research participants, prospective participants and/or their advocacy groups regarding the scientific and ethical aspects of human research.**

**ELEMENTS**

V.2.A. The Organization has a program for enhancing the public understanding of the everyday relevance of scientific inquiry and the fruits of science, and the critical role played by volunteer participants.

V.2.B. The Organization has a program for mutual exchange of views with participants and prospective participants regarding research participation, and ways of enhancing the participant’s experience as a research volunteer.

V.2.C. The Investigator or Sponsor prepares, and the IRB approves, information for research participants, prospective participants, and their representatives to understand the HRPP's arrangements for protecting participants' privacy and safeguarding them from research risks.

V.2.D. The Investigator or Sponsor prepares, and the IRB approves, information for participants and prospective participants regarding informed consent, the importance of adherence to instruction, and mechanisms for open communication regarding unusual or unexpected physical, mental or emotional symptoms or occurrences, including any difficulty adhering to the protocol.

## SECTION 5

## ACCREDITATION PROCESS, SITE VISITS AND SITE VISITORS

The initial step in the accreditation process is for an Organization to engage in a thorough self-study. This will enable the Organization to identify and remedy weaknesses and to determine the appropriate operational unit for accreditation of its HRPP. Prior to seeking accreditation, the Organization should develop a clear concept of the programmatic entity that would be seeking accreditation.

A site visitor will evaluate the program's performance with respect to each Standard. The Elements for each Standard identify the more concrete practices that are evidence of the Standard in the program's daily operation. Each Organization shall be evaluated initially by a team of not fewer than two site visitors chosen by AAHRPP. At its option, AAHRPP may use one site visitor for periodic or special site visits after the initial site visit has been concluded, or to visit a small and or remote facility. No HRPP shall be accredited by AAHRPP without a site visit. Accredited HRPPs and those on provisional status will be routinely revisited at appropriate intervals. Additional interim or follow-up visits may be required to confirm correction of deficiencies or if there are major changes in programs or facilities.

AAHRPP shall not permit or arrange for an evaluation of an Organization by any visitor who—

(1) is employed or retained by the Organization;

(2) is employed or retained by the same person or institution or agency that owns, manages or operates the HRPP ("agency" shall be interpreted as the immediate government or private entity which has administrative authority over the site visitor, e.g., Department of Army, Department of Health and Human Services, State University System, Company, Corporation, Foundation, etc.); or

(3) is employed or retained by, or the owner of, another organization that has a financial interest in the outcome of the site visit to the Organization's HRPP.

When a site visitor is employed or retained by an entity that is in direct commercial competition with the Organization to be evaluated, AAHRPP shall ensure that it identifies, minimizes and manages any real or apparent conflict of interest.

AAHRPP must have sufficient information to evaluate adequately an applicant's program and facilities. In general, this will require that site visitors be permitted to enter any and all facilities in which participants are observed, treated or interviewed, as well as administrative work areas. Further, the site visitors must be provided with access to all relevant records, policies, procedures, minutes, budgets, sample protocols, consent and authorization forms and other materials. To perform these tasks, the site visitors should sign confidentiality agreements prior to the visit.

AAHRPP will not accredit Organizations that cannot be thoroughly evaluated.

No member, employee or consultant to AAHRPP shall have authority to perform or conduct on behalf of AAHRPP an evaluation of any Organization except upon and in accordance with an assignment made by AAHRPP.

## SECTION 6

## GRANTING OR DENYING ACCREDITATION

The AAHRPP Board of Directors shall have the authority to review all applications and site visit reports and determine the accreditation status of individual Organizations, subject to the rights to appeal otherwise provided for in these Standards.

The Board of Directors may delegate to AAHRPP committees the roles, responsibilities, and authorities to facilitate the efficient operation of the accreditation processes. The Executive Committee of the Board of Directors may act on behalf of the Board of Directors in confirming actions relative to granting accreditation.

## SECTION 7

## ACCREDITATION STATUS

Accreditation may be granted, withheld or revoked by AAHRPP. Once granted, accreditation may be revoked based on any untoward event, or material change in the administration, financing or operation of a human research program, which in the opinion of AAHRPP is sufficient to warrant such revocation. Any accredited Organization shall be evaluated as often as deemed necessary by AAHRPP to protect the rights and welfare of research participants.

Revocation: Accreditation may be revoked by AAHRPP at any time for due cause. A previously accredited Organization cannot be reverted to provisional accreditation. AAHRPP may advise an accredited Organization that it has been placed on probation, the proposed reasons for revoking accreditation, and that if the specific deficiencies are not corrected within a specific period to be determined by AAHRPP, not to exceed 6 months, accreditation will be revoked. If all probationary deficiencies have been satisfactorily corrected at the time of the site revisit but additional deficiencies of a serious nature are noted, an additional probationary period, not to exceed 6 months, may be granted to correct the new deficiencies. Notice of probation shall be made known only to the Organization and to AAHRPP.

Provisional accreditation status may be granted to a new applicant by AAHRPP for a period to extend not more than 12 months if, in the opinion of AAHRPP, such status is justified. Immediately after the expiration of that period, accreditation must be either withheld or granted.

At its option and based upon the circumstances of each case, AAHRPP shall decide whether an additional site visit is needed before taking action on any Organization that is on provisional or probationary status.

## SECTION 8

## HEARINGS AND APPEALS

Before rendering any decision to withhold or revoke accreditation, AAHRPP shall notify the Organization in writing of the proposed decision and the factual findings and reasons supporting the proposed decision. AAHRPP shall also indicate in such notice that all reports, documents, and records considered in reaching its proposed decision and factual findings will be made available promptly or supplied to the Organization or its representative upon receipt of a written request. Such notice shall be sent to the Organization utilizing a return receipt mechanism that confirms delivery and indicates the date of delivery (e.g., registered mail, certified mail, etc.). Within 30 days after receipt of such notice, the Organization may offer written evidence or argument tending to refute or overcome the factual findings and proposed decision of AAHRPP. In addition, or in the alternative, the Organization may apply in writing for an oral hearing.

If requested, AAHRPP shall hold such hearing at its next scheduled meeting after receipt of such request, and the Organization shall be given an opportunity at such hearing to present evidence or argument tending to refute or overcome the factual findings and proposed decision. The Organization may be represented by counsel. Within 30 days after its meeting, AAHRPP shall render its decision after considering all the facts and matters before it, and shall send its decision to the Organization utilizing a return receipt mechanism that confirms delivery and indicates the date of delivery. In the event of the failure of the Organization to make timely submission of evidence or argument, the initial decision shall be final.

If the decision of AAHRPP is to withhold or revoke accreditation, the Organization shall be entitled to an appeal to the Board of Directors. Such appeal shall be initiated by a written request to the Board of Directors within thirty (30) days after receipt of the decision of AAHRPP. The hearing, notice, and decision provisions of an appeal to the Board of Directors shall be the same as noted above.

## SECTION 9

## CERTIFICATES

AAHRPP shall issue a certificate of accreditation to each accredited Organization. If an Organization shall have its accreditation revoked, the certificate of accreditation shall be returned to AAHRPP. Organizations that are on provisional status are not entitled to receive certificates of accreditation.

Display or use of any outdated, revoked, defaced or fraudulent AAHRPP certificate or of facsimiles that might deceive or mislead potential participants, sponsors, or other persons, shall be considered a serious offense with the potential for harming the public confidence in research and the research protection system. Appropriate legal action may be taken by AAHRPP based on the facts of any such deception.

## SECTION 10

## CONFIDENTIALITY

All proprietary information made available by Organizations to AAHRPP or its site visitors will be kept confidential. No site visitor will take away or retain copies of any Organization's confidential documents. No site visitor shall disclose any of his or her findings to any person or agency except AAHRPP. Site visitors or other AAHRPP employees or contractors who fail to adhere to this policy will be discharged and not subject to further use or employment by AAHRPP.

All files and records of AAHRPP shall be held in confidence by AAHRPP and its members, and no such confidential data shall be released by AAHRPP except pursuant to direction by the Board of Directors or under the order of a court of law or the execution of a valid search warrant.